

**Rejection of Claims under 35 U.S.C. § 102(e).**

Claims 1 to 13, 22, 26 and 27 are rejected under 35 USC §102(e) as being anticipated over De Wille et al. (US 5,597,595). Applicant respectfully traverses this rejection.

While it is not believed to change the rejection, Applicants note that the Examiner is believed to be incorrect in application of the AIPA to the present filing. While the parent application (USSN 09/485,898) now allowed as US 6,383,473 was filed prior to the November 29, 2000 date, the present application, as a divisional was filed on January 17, 2002 thereby having the AIPA apply.

Until the present invention there was no means available to the skilled artisan to readily determine how to reduce tooth erosion in a solid or semi-solid composition. The present invention requires only the addition of calcium to an acidic composition, not a combination of calcium with another acidulant.

It should be noted that the total amount of calcium and specified acids, expressed either as w/w percentages of the composition or as absolute quantities, in the prior art compositions are not relevant to the determination of patentability unless they are expressed in such a way as to allow the calcium to acid molar ratio to be measured and that ratio falls within the range 0.3 to 0.65 while conferring a pH in the range 3.5 to 4.5 as claimed in claim 1.

The concept of identifying a composition which is effective against tooth erosion by reference to calcium:acid molar ratio and their pH in solid or semi-solid compositions is believed to be novel over the cited De Wille et al. reference.

US 5,597,595 ('595) De Wille et al. does not disclose to the skilled artisan how to control the Ca/acid mole ratio and pH of a composition. Consequently, there is no disclosure in the document relating to calculation of the molar ratio and a balancing of these factors for the end use of the compositions. De Willie et al. is not related to inhibition or reduction of tooth erosion, but to compositions supplemented with calcium and vitamin D. Therefore, in De Willie et al., when an acid is added to the composition it is to maintain calcium solubility, to complement flavour, to control microbial growth and enhance the role of the preservatives (see column 24, lines 62-67). The Vitamin D is also present to enhance the absorption of calcium.

The Examiner states that a "powdered beverage concentrate comprising calcium compound (i.e. calcium glycerophosphate) and an acid (citric acid and lactic acid)" are disclosed. The molar ratio of the calcium to acid in this Example, Example 7 is also stated by the Examiner to be "about 0.5". Applicants disagree with this calculation. The mole ratio in Example 7 is above 0.7, not 0.51, as 60% lactic acid is used (total acids = 1.89 moles

and total calcium = 1.39moles). The 0.71 ratio is above the claimed ratio of 0.3 to 0.65 as claimed in claim 1 and would not meet the pH requirements, and is therefor not anticipatory of the invention. Similarly, the Examiners rejection of claims 2 to 4 and 26 to 27 are also not anticipatory.

The molar ratio calculations for Example 7 of De Wille et al are shown below:

Calcium glycerophosphate molecular wt = 210  
Moles of Ca:  $291.6\text{g}/210 = 1.39$

Lactic acid powder molecular wt = 90  
Moles lactic acid:  $181.3\text{g}/90 = 2.01$   
since 60% lactic acid is used, the moles of lactic acid =  $2.01 \times 0.6 = 1.21$

Citric acid molecular wt = 192  
Moles citric acid =  $130.2\text{g}/192 = 0.68$

Total moles of acid =  $1.21 + 0.68 = 1.89$

Molar Ratio of Calcium : Acid =  $1.39 : 1.89 = 0.74$

what if 88%  
= 1.76  
1.76  
AS = 1.76  
10.5/176 = 0.06

The absolute amount of calcium present in a composition prepared according to the invention herein is not critical. It is the molar ratio of calcium to total acids. It is this recognition, *the molar ratio of calcium to total acid* in a solid or semi-solid composition, which is the heretofore an unrecognized invention to reduce tooth erosion. The prior art does not disclose preparation of such a composition, nor the use of such a composition having these defined parameters.

In light of these remarks, Applicants respectfully request reconsideration and withdrawal of the rejection to the claims under 35 USC §102(e).

**Rejection of Claims under 35 USC § 103(a).**

Claims 1 to 13, 22, 26 and 27 are rejected under 35 USC §103(a) as being unpatentable over Burkes et al. (US 5,445,837, hereinafter '837). Applicant respectfully traverses this rejection.

Calcium-containing acidic drinks are well known in the art from the standpoint of nutritional supplementation (as shown in the cited US patents). The concept of identifying compositions effective against tooth erosion by reference to a calcium:acid molar ratio and

pH is believed to be both novel and non-obvious, particularly as they relate to solid or semi-solid compositions.

The Burkes et al. '837 patent relates to stable sweetener compositions providing a bioavailable source of calcium. The '837 patent is particularly concerned with the overall level of calcium citrate maleate (CCM), where the mole ratio of calcium to citric to malic acid is defined relative only to the CCM itself as this is the active calcium component as a dietary supplement. The '837 patent does not specifically have anything to do with the ratio of calcium to total acid present in the composition. CCM is a relatively good tasting calcium source which can be readily used in beverages, in contrast to the traditional calcium supplement calcium carbonate. The Assignees, Procter and Gamble Company have a large portfolio, approximately 25 US patents relating to CCM ranging from manufacture of, compositions and use thereof. Should the Examiner wish a listing of these patents, please contact the undersigned at the number indicated below.

The resulting pH of the sweetener compositions of the '837 patent is stated in the specification (see column 9, lines 39 to 44) to be "less than or equal to about 3.8. Preferably the pH is less than or equal to about 3.4, and more preferably less than or equal to about 3.2. Typically, the pH will range from about 2.5 to about 3.8". The general disclosure does not provide any additional information, which enables one to calculate the calcium to acid molar ratio.

In the Examples Section of the '837 patent, only Example 7 discloses a pH above 3.5. According to calculations, the sweetener composition of Example 7 will provide a calcium to acid molar ratio above 0.8, hence outside of the claimed range herein.

The molar ratios of the composition of the Burkes et al. '837 patent are outside the claimed invention. The lowest ratio which one can calculate in Burkes et al. patent is in example 7 which has a ratio of 0.81. The Examiner asserts that there is motivation for one skilled in the art to optimize amounts to improve the stability of CCM, however our invention does not relate to stabilizing the calcium source. There is no motivation for a person skilled in the art to take the teaching of Burkes et al. and desire to control the ca/acid mole ratio and pH to arrive at the compositions and use of the present invention.

The present invention provides for a solid or semi-solid composition wherein the calcium and acidulant are in a defined molar range of from 0.3 to 0.65, with control of pH from 3.5 to 4.5 for the purpose of prevention or reduction of tooth erosion when using such as composition. There is no need for additional acid, nor for the use of large relative and absolute quantities of

calcium. The purposes of compositions, which have those characteristics, are different. The skilled artisan would not be motivated to use the teachings of those types of references to achieve the invention claimed herein. The problem is different, which results in a different solution. While US law is not directed to a problem-solution analysis, for the purposes herein the disclosures of the cited US Patents do not provide enablement to direct the skilled artisan to achieve the desired results. One would not be led to achieve both a control of the molar ratio of calcium:acid as well the pH of a composition without a particular motivation, such as that described herein.

In view of these remarks Applicant respectfully requests that the rejection to the claims under 35 USC §103 be withdrawn.

#### Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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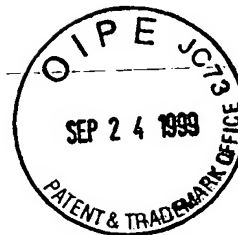
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21 September 1999

AGENT/ATTORNEY FOR APPLICANT

DATE



Attorney Docket No.: C70259

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Parker, D.

21 September 1999

Serial No.: 09/125,471

Group Art Unit No.: 1761

Filed: 19 August 1998

Examiner: S. Rose

For: Liquid Oral Compositions Comprising a Calcium Compound and an  
Acidulant

Assistant Commissioner of Patents

Washington, D.C. 20231

RESPONSE

Sir:

In response to the Examiner's Action mailed 30 March 1999, having a shortened  
statutory period of 3 months, please enter the following Remarks into the record. Also  
enclosed herewith is a petition for a three (3) month extension of the shortened statutory  
period set by the Examiner and authorization to charge the required fee to the indicated  
deposit account.

REMARKS

Claims 1 to 18, and 23 to 45 are in the application. No claim has been amended.  
A supplemental IDS statement and PTO 1449 form accompanies this response.  
References will be sent under separate cover. Applicants have not received a signed  
PTOL 1449 form from the Examiner which cited the references from the PCT search  
report. A replacement PTOL form for those references accompanies this response.

**Rejection under 35 USC §102 (b)/103(a)**

Claims 1 to 18, and 23 to 45 are rejected under 35 USC §102(b) as anticipated by,  
or in the alternative under 35 USC §103(a) as obvious over Dake et al., Burkes et al.,

Andon, Meyer et al., Keating, de Wille et al. (I), Akahoshi et al., de Wille et al. (II), each taken alone or with Lussi et al (I-II). Applicants respectfully traverse these rejections.

According to the Examiner, each US patent describes a composition comprising a calcium compound, an acidulant and an acidic oral liquid adjusted to a pH falling within the claimed range. While the references each disclose some aspect of the claimed invention, the Examiner has not addressed with specificity whether any of these citations disclose a composition as defined by Applicants claims.

It is believed that none of these citations provide for a specific disclosure of a composition comprising a calcium compound and an acidulant such that the molar ratio of calcium is in the range 0.3 to 0.55 and having a pH in the range 3.5 to 4.5 (as claimed in claim 1).

It is further believed that none of the cited US patents are concerned with dental erosion, the claimed method of use (claim 14) for such a composition.

The present invention is directed toward technology used commercially in Applicants products, presently on sale in the United Kingdom. This invention is applicable, however, to any acid based liquid composition for oral use to reduce tooth erosion. It relies upon the addition of calcium to acidic compositions at levels which maintain a balance between efficacy with respect to reduced dental erosion and palatability, and is governed by control of pH.

It is recognized that calcium-containing acidic drinks are well known from the standpoint of nutritional supplementation (as shown in the cited US patents). The concept of identifying compositions effective against tooth erosion by reference to calcium:acid molar ratio and pH is believed to be both novel and non-obvious.

In order to address these rejections for both novelty, and obviousness under 35 USC §102 and §103, Applicants have set forth below what it is believed the cited patents describe. Specifically, whether they disclose any compositions falling within the claimed pH range and/or have a calcium to acid molar ratio in the range 0.3 to 0.55.

The Dake et al. patent, US 5,424,082 relates to beverages supplemented with calcium and vitamin C and addresses the problem of discolouration due to vitamin C oxidation. It does not disclose nor suggest dental erosion due to acid. The general disclosure in the description allows for compositions having a pH in the claimed range of 3.5 to 4.5 but does not include any specific information which discloses compositions having a calcium to acid molar ratio in the range 0.3 to 0.55. In common with many of

the other references, the disclosure of sources of calcium and acid components are not expressed in such a way that the molar ratio of calcium to acid can be calculated. This is a clear indicator that the essential technical features of the invention have not been disclosed, and that the concept underlying the present invention is novel and inventive.

Looking for a specific disclosure to calculate the molar ratio, for instance in the examples section, Examples 2 and 3 must be discarded as they disclose the presence of 1.1% wt. fruit juice concentrate but do not detail the source of the acid component such that the molarity of the acidulant cannot be calculated.

Examples 1 and 4 disclose compositions having a calcium to acid molar ratio of less than 0.3. Accordingly, even if it is assumed that the pH of these compositions lies in the range 0.35 to 0.45, the calcium to acid molar ratio falls outside the claimed range herein.

The Burkes et al. patent, US 5,445,837 relates to stable sweetener compositions providing a bioavailable source of calcium and including an acidulant in the form of citric acid and malic acid. The pH of the sweetener compositions is less than or equal to about 3.8, preferably less than or equal to about 3.4 and more preferably less than or equal to about 3.2 (see column 9). The general disclosure does not provide information which enables calcium to acid molar ratios to be calculated. Turning to the Examples, only Example 7 discloses a pH above 3.5. According to calculations, the sweetener composition of Example 7 gives a calcium to acid molar ratio above 0.8, hence outside of the claimed range herein.

The Andon patent, US 5,468,506 also discloses a sweetener composition providing a bioavailable source of calcium and includes an acidulant in the form of citric acid and malic acid. The pH disclosure is as for Burkes et al. (column 7). The general description does not provide sufficient information to determine the calcium to acid molar ratio and pH of compositions according to the claimed invention. There are no specific examples given. Hence it is not an enabling disclosure for purposes of the present invention.

The Meyer et al. patent, US 5,474,793 discloses a process for preparing calcium-supplemented, ready-to-serve, fruit juice beverages. In addition to fruit juice, acid is present in the form of added citric and malic acid. The beverage compositions prepared according to the process should have a pH no higher than about 4.5 (column 7). pH can be controlled by rate of addition of calcium, the total level of calcium and/or the acid level. There is however, no teaching regarding the ratio of calcium to total acid.

The three Examples (Embodiments) are sufficiently detailed to allow the calcium to acid molar ratio to be calculated although it should be noted that pH is merely given as being "less than about 4". Accordingly, Embodiment 1 has a calcium to acid ratio of 0.75; Embodiment 2 has a ratio of greater than 1; Embodiment 3a has a ratio of 0.72, and Embodiment 3b has a ratio greater than 1. Thus, Meyer et al. contains no specific disclosure of a composition as claimed in claims 1 to 13. Further, since Meyer et al. does not relate to tooth erosion, it contains no teaching for the method of use claims, claims 14 to 18 and 23 to 45.

The Keating patent, US 5,500,232 discloses calcium fortified acid beverages in which the calcium source is a combination of calcium hydroxide and calcium glycerophosphate and the acidulant is a combination of citric acid and fumaric acid. It does not relate to tooth erosion and, in common with the other patent references relied on, is not relevant to the method claims.

Amounts of calcium and acid sources are given but there is no discussion of relative amounts of calcium and total acid. pH (see column 3) is between 2 and 5, preferably from about 3 to about 4.3. Ingredients are given for 3 flavoured calcium fortified beverages, strawberry/cherry, raspberry and mandarin orange (columns 4 & 5); according to calculations each has a calcium to acid molar ratio of 0.7. Thus, if it is assumed that these have a pH falling within the range 3.5 to 4.5, these compositions do not have a calcium to acid molar ratio as required by claims 1 to 13. The remaining examples do not provide relevant information for calculating molar ratios.

The De Wille et al (I) patent, US 5,597,595 discloses a liquid beverage concentrate and a beverage containing the concentrate fortified with calcium and vitamin D. The calcium source is calcium glycerophosphate and the pH lies in the range 2.8 to 4.6. An acidulant may be present.

The general disclosure is not enabling for the calculation of calcium to acid molar ratios. Under the heading 'Embodiments of the Invention' (column 38) are several Bills of Materials for prototype low pH beverages. Calculation of calcium to acid molar ratio for each of the beverages disclosed in Tables 18, 19, 20 and 21 gives the ratio equal to 0.63 which is above the 0.55 limit of claims 1 to 13. While this may place the compositions within the claimed range for the method claims, this reference is not considered relevant to the obviousness rejection as it does not relate to, nor is there any mention of tooth erosion.



Of the remaining Examples, only Example 7 provides sufficient information for calculation of a calcium to acid molar ratio (Table 25). Calculation gives the ratio at 0.71 for this powdered concentrate.

The Akahoshi patent, US 5,690,975 discloses a method for producing a calcium enriched fermented milk or fermented milk drink containing calcium and lactic acid from milk as acidulant. A syrup containing a further acid source in the form of fruit juice may also be present. The pH of the beverage compositions is not specified but there is reference to pH in the range 3.5 to 4.2 in the context of pectin stability (see Column 2). There is no information in the specification which allows calcium to acid molar ratios to be calculated.

The DeWille (II) patent, US 5,817,351 discloses a low pH (2.8 to 4.6) beverage for supplementation of dietary calcium in which the source of calcium is calcium glycerophosphate. Acidulants, preferably as citric acid and lactic acid may be present. The only enabling examples with respect to calculation of calcium to acid molar ratios are identical to those in DeWille (I). This reference is not considered relevant to the obviousness rejection as it does not relate to, nor is there any mention of tooth erosion.

In summary, none of the cited US patents discloses a composition having a calcium to acid ratio in the range 0.3 to 0.55 and a pH in the range 3.5 to 4.5. None of the references is therefore novelty destroying, or anticipatory, within the meaning of §102(b) for any of claims 1 to 13. Furthermore, since none of the references relate to tooth erosion, there is no disclosure which would render the claims anticipated within the meaning of §102(b) for any of claims 14 to 18 and 23 to 45. Nor, does any of these references taken either alone or in combination with another such reference either teach, or motivate the use of a method as claimed in any of claims 14 to 18 and 23 to 45 within the meaning of §103.

With regard to the §103 objection based upon Lussi (I) and (II), these papers concern the prediction of the erosive potential of beverages due to acid. These references are predictive of the problem of tooth erosion. They do not contain any teaching regarding how the problem can be solved. In particular, they do not suggest use of calcium in beverage compositions for reducing tooth erosion, let alone any suggestion that tooth erosion may be reduced by balancing calcium content, acid content and pH of acid compositions according to the invention as claimed. A person of average skill in the

art wishing to reduce the erosive potential of acid compositions would find nothing to motivate him in Lussi (I) or (II) which would cause him to even consider any of the cited US patent references.

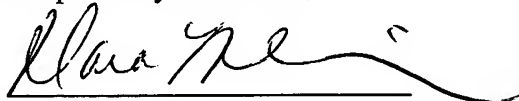
While acidic liquid compositions for oral use containing calcium were well known at the date of the present invention, the skilled person confronted with the task of preparing an acidic composition which inhibits dental erosion caused by acid would obtain no guidance from the prior art which would lead him to a composition which confers the desired effect through use of calcium with strict control over pH and calcium to acid balance.

In light of these remarks, Applicants respectfully request reconsideration and withdrawal of the rejection to the claims under 35 USC §102(b) and under 35 USC §103(a).

#### Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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Art Unit 1614

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-18 and 23-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of each of the U.S. patents to Dake et al., Burkes et al., Andon, Meyer et al., Keating, de Wille et al. (I), Akahoshi et al., de Wille et al. (II) each taken alone or taken with Lussi et al. (I-II) each describing an encompassed species of a calcium compound, an encompassed species of an acidulent and an encompassed species of an acidic oral liquid adjusted to an encompassed acid pH range, the method claims 14-18 and 33-45 being motivated and predicted for the tooth erosive potential of such acidic liquid beverages by Lussi et al. (I-II).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6 P.M.

Art Unit 1614

decrease erosive potential, counsel and Examiner will have to work together to see if we can find justification for a 37 CFR 1.75(e) Jepson type improvement in the advantage of less calcium. There of course is less economic waste from the excess calcium.

It is not clear to the Examiner that that is the basis for applicant's argument and clarification is requested. Is it applicant's position that the higher amounts of calcium in the prior art is a negative teaching away from less calcium? Let's see if we have any novelty present.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Serial No. 09/125,471

-3-

Art Unit 1614

for such acid beverages. Herein, there is 0.1% ~~white~~<sup>✓</sup> weight to 4% ~~white~~<sup>✓</sup> weight acid, according to page 4 lines 20-24. Since the cited prior art relies on includes, stated percentages of calcium and of acid for example Keating 5,500,232 (note moles on columns 5 and 6 of both calcium and acid), a calculation must be made of the percentage of calcium and acid herein to determine if there is novelty.

The Keating patent has the moles herein, and the argument that it "does not relate to tooth erosion" is untenable with respect to the composition claims. The method claims are viewed as inherent under Ex parte Novitsky 26 USPQ 2d 1398.

The Lussi (I-II) papers underscore the technical problem encountered by tooth erosive acid in beverages, at low pH as herein, and in the cited prior art. Applicant's solution to the problem is to add less concentration of calcium ion than in the working examples of the references, although the claims fail to bear this out. Once applicant submits a Rule 132 Declaration calculating the minimum and maximum percentages of each of calcium and acid encompassed by these claims, and for each reference, both parties will have a clear picture of whether or not novelty is present. As to whether or not the last sentence on page 9 is to be taken as the basis for an argument that the higher concentration of calcium in the cited prior art are a negative teaching away and are not justified as they do not

Art Unit 1614

The following is a statement of reasons for the indication of allowable subject matter:

A Jepson type 37 CFR 1.75(b) improvement for the claimed methods of claims 42-45 of reducing tooth erosion, when there will be recited a positive step of contacting the tooth enamel subject to tooth erosion, in the enabled manner disclosed on pages 8, 9, 11, 12 and 15, with the recited mole ratio and a negative proviso focused on the last sentence on page 9 --said calcium acid molar ratio of about 0.5 achieving no decrease in erosive potential by increasing the calcium:acid molar ratio beyond about 0.5, said acidic calcium tooth erosion inhibiting composition being free of excess calcium present beyond 0.8 mole per mole of acid--.

The September 24, 1999 request for reconsideration has been carefully considered, but if the calcium to acid molar ratio in the range 0.3 to 0.55 is to be taken as stated in the last sentence on page 9 "no justifiable decrease in erosive potential can be achieved by increasing the calcium acid molar ratio much beyond this point", then the specification and claims herein must be translated by someone into an answer to these questions:

Q.: What is the enabled percentage of acid? What are the enabled percentages of calcium? It is admitted prior art set forth in the specification on page 1 lines 20-24 that the prior art describes 0.02% white weight to 2% white weight calcium ion



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21 November 2000

AGENT/ATTORNEY FOR APPLICANT

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Attorney Docket No.: C70259

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Parker, D. 21 November 2000  
Serial No.: 09/125,471 Group Art Unit No.: 1614  
Filed: 19 August 1998 Examiner: S. Rose  
For: Liquid Oral Compositions Comprising a Calcium Compound and an  
Acidulant

Assistant Commissioner of Patents  
Washington, D.C. 20231

RESPONSE

Sir:

In response to the Examiner's Action mailed 30 May 2000, having a shortened statutory period of 3 months, please enter the following Remarks and Amendments into the record. Enclosed herewith is a petition for a three (3) month extension of the shortened statutory period set by the Examiner and authorization to charge the required fee to the indicated deposit account. A Notice of Appeal also accompanies this response.

In the Claims:

Please cancel Claims 1 to 14, and 23 to 37, 40, and 41.

Please amend the following claims:

Please change the claim dependency of claim 15 from "Claim 14 " to -- Claim 42 --.

Please change the claim dependency of claim 16 from "Claim 14 " to -- Claim 42 --.

Please change the claim dependency of claim 17 from "Claim 14 " to -- Claim 42 --.

Please change the claim dependency of claim 18 from "Claim 14 " to -- Claim 42 --.

Please change the claim dependency of claim 38 from "Claim 37" to -- Claim 18 --.

Please change the claim dependency of claim 39 from "Claim 33" to -- Claim 42 --.

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Claims 42 (amended) A method of reducing the tooth erosion properties of an acidic oral composition used for oral administration, [which method comprises] comprising adding calcium to the acidic liquid oral composition wherein the calcium is present in the range of 0.3 to 0.8 mol per mol of acid and the pH of the composition is from 3.5 to 4.5; and adjusting the pH, if necessary or desired, by [adding an alkali to adjust the pH from 3.5 to 4.5; ] by addition of an alkali such that the pH of the resulting composition is in the range of 3.5 to 4.5; subject to the proviso that if the composition is a fruit-containing liquid having a fruit content of 25 to 100% by weight and an acid content of at least 5g/litre (calculated as tartaric acid), then it contains less than 2g/litre of dissolved calcium phosphate.

43 (amended). A method of reducing the tooth erosion properties of an acidic oral composition used for oral administration, [which method comprises] comprising adding calcium to the acidic liquid oral composition wherein the calcium is present in the range of 0.3 to 0.55 mol per mol of acid and the pH of the composition is from 3.5 to 4.5, and adjusting the pH, if necessary or desired, [adding an alkali to adjust the pH from 3.5 to 4.5; ] by addition of an alkali such that the pH of the resulting composition is in the range of 3.5 to 4.5.

44. A method of reducing tooth erosion in a human caused by acid in an orally administered composition which method comprises orally administering to said human a liquid composition comprising a calcium compound and an acidulant, wherein the calcium is present in the range 0.3 to 0.8 mol per mol of acid and the pH of the composition is from 3.5 to 4.5; subject to the proviso that if the composition is a fruit-containing liquid having a fruit content of 25 to 100% by weight and an acid content of at least 5g/litre (calculated as tartaric acid), then it contains less than 2g/litre of dissolved calcium phosphate.

45 (amended). A method of reducing tooth erosion in a human caused by acid in an orally administered composition which method comprises orally administering to said human a liquid composition comprising a calcium compound and an acidulant, wherein the calcium is present in the range 0.3 to 0.55 mol per mol of acid and the pH of the composition is from 3.5 to 4.5.



Please add the following claims:

46. The method as claimed in claim 44 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.
47. The method as claimed in claim 44 in which the pH of the composition is not more than 4.
48. The method as claimed in Claim 44 in which the pH of the composition is from 3.7 to 3.9.
49. The method as claimed in Claim 44 in which the acidic liquid composition is a beverage.
50. The method as claimed in Claim 49 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.
51. The method as claimed in Claim 44 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.
52. The method as claimed in Claim 44 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.
53. The method as claimed in Claim 44 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.
54. The method as claimed in Claim 42 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.
55. The method as claimed in Claim 42 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.

56. The method as claimed in claim 43 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.

57. The method as claimed in claim 43 in which the pH of the composition is not more than 4.

58. The method as claimed in Claim 43 in which the pH of the composition is from 3.7 to 3.9.

59. The method as claimed in Claim 43 in which the acidic liquid composition is a beverage.

60. The method as claimed in Claim 59 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.

61. The method as claimed in Claim 43 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.

62. The method as claimed in Claim 43 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.

63. The method as claimed in Claim 43 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.

64. The method as claimed in claim 45 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.

65. The method as claimed in claim 45 in which the pH of the composition is not more than 4.

66. The method as claimed in Claim 45 in which the pH of the composition is from 3.7 to 3.9.

67. The method as claimed in Claim 45 in which the acidic liquid composition is a beverage.

68. The method as claimed in Claim 67 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.

69. The method as claimed in Claim 45 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.

70. The method as claimed in Claim 45 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.

71. The method as claimed in Claim 45 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.

#### **REMARKS**

Claims 15 to 18, 38, and 39, and 42 to 45 plus newly added claims 46 to 71 are in the application. Claims 1 to 14, and 23 to 37, 40, and 41 have been cancelled. Applicants respectfully request entry of the newly added claims in light of the cancellation of the composition claims and the discussion at the interview of 28 June 2000. A clean copy of the claims remaining in the application is attached as an appendix. No additional fees for the amended claims is believed necessary as the total number of claims added is less than the number of claims being cancelled.

Applicants thank the Examiner for the Interview of 28 June 2000. In response thereto, Applicants have cancelled the composition claims as suggested, and have amended several of the method of use claims to more particularly point out and distinctly claim the invention. Applicants reserve their right to file divisional or continuation application on cancelled or deleted subject matter.

#### **Rejection under 35 USC §102 (b)/103(a)**

Claims 1 to 18, and 23 to 45 are rejected under 35 USC §102(b) as anticipated by, or in the alternative under 35 USC §103(a) as obvious over Dake et al., Burkes et al., Andon, Meyer et al., Keating, de Wille et al. (I), Akahoshi et al., de Wille et al. (II), each taken alone or with Lussi et al (I-II). Applicants respectfully traverse these rejections.

According to the Examiner, each US patent describes a composition comprising an "encompassed species of a calcium compound, an encompassed species of an acidulant and an encompassed species of an acidic oral liquid adjusted to an encompassed acid pH range". The method claims 14 to 18 and 33 to 45 are included in this rejection as "being motivated and predicted for the tooth erosive potential of such acidic liquid beverages by Lussi et al (I and II).

As discussed in the Interview, the prior art rejection appears to indicate that the present invention is directed to a reduction in the concentration of calcium over that disclosed in the prior art, while in practice, a tooth erosion inhibiting beverage of the present invention may have a lower calcium concentration than generally disclosed in the art of calcium supplemented beverages, this is not what the present invention is directed towards.

The primary objective of a calcium supplementation would be to maximize calcium levels; in this invention calcium is used as a means for balancing acidity and pH within the composition. The higher the acid content, the more calcium would be required in order to stay within the defined molar ratio range. The total amount will, however be limited to some extent by the overall pH requirement. This concept is not described, nor taught by any of the prior art.

The total amount of calcium and specified acids, expressed either as w/w percentages of the composition or as absolute quantities, in the prior art compositions are not relevant to the determination of patentability unless they are expressed in such a way as to allow the calcium to acid molar ratio to be measured and that ratio falls within the range 0.3 to 0.80 (or .55) while conferring a pH in the range 3.5 to 4.5 as claimed in claims 42 or 43. The calculations presented in the Interview clearly demonstrate that none of the cited references disclose the composition nor the method(s) of the invention as claimed herein. However, in order to advance prosecution on the merits, Applicants have cancelled the composition claims and will continue prosecution in a continuation application.

The concept of identifying compositions which are effective against tooth erosion by reference to calcium:acid molar ratio and their pH is believed to be both novel and non-obvious over the cited references.

Applicants incorporate by reference their data presentation of representative examples of the cited prior art in their handout of the Interview of 28 June 2000. Claims 42 and 43 (and those dependent thereon) are directed to a method of reducing the tooth erosion properties of an oral composition which will be used in oral administration,

whereas Claims 44 and 45 (and those dependent thereon) are directed to the actual method of use by a patient of the composition for reduction of tooth erosion.

In view of this data, and recognition that the prior art does not teach reduction of tooth erosion by use of a particular composition having the defined parameters, the rejection to the claims under 35 USC §102/103 is believed removed. Reconsideration and allowance of the claims in the application is respectfully requested.

### Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



Dara L. Dinner  
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Claims in USPN 09/125,471 as of this Response and Amendment dated 21 November 2000 (not in sequential order)

42. A method of reducing the tooth erosion properties of an acidic oral composition used for oral administration comprising adding calcium to the acidic liquid oral composition wherein the calcium is present in the range of 0.3 to 0.8 mol per mol of acid and the pH of the composition is from 3.5 to 4.5; and adjusting the pH, if necessary or desired, by addition of an alkali such that the pH of the resulting composition is in the range of 3.5 to 4.5; subject to the proviso that if the composition is a fruit-containing liquid having a fruit content of 25 to 100% by weight and an acid content of at least 5g/litre (calculated as tartaric acid), then it contains less than 2g/litre of dissolved calcium phosphate.

15. The method as claimed in claim 42 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.

16. The method as claimed in claim 42 in which the pH of the composition is not more than 4.

17. The method as claimed in Claim 42 in which the pH of the composition is from 3.7 to 3.9.

18. The method as claimed in Claim 42 in which the acidic liquid composition is a beverage.

38. The method as claimed in Claim 18 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.

39. The method as claimed in Claim 42 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.

54. The method as claimed in Claim 42 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.

55. The method as claimed in Claim 42 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.

43. A method of reducing the tooth erosion properties of an acidic oral composition used for oral administration comprising adding calcium to the acidic liquid oral composition wherein the calcium is present in the range of 0.3 to 0.55 mol per mol of acid and the pH of the composition is from 3.5 to 4.5, and adjusting the pH, if necessary or desired, by addition of an alkali such that the pH of the resulting composition is in the range of 3.5 to 4.5.

56. The method as claimed in claim 43 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.

57. The method as claimed in claim 43 in which the pH of the composition is not more than 4.

58. The method as claimed in Claim 43 in which the pH of the composition is from 3.7 to 3.9.

59. The method as claimed in Claim 43 in which the acidic liquid composition is a beverage.

60. The method as claimed in Claim 59 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.

61. The method as claimed in Claim 43 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.

62. The method as claimed in Claim 43 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.

63. The method as claimed in Claim 43 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.
44. A method of reducing tooth erosion in a human caused by acid in an orally administered composition which method comprises orally administering to said human a liquid composition comprising a calcium compound and an acidulant, wherein the calcium is present in the range 0.3 to 0.8 mol per mol of acid and the pH of the composition is from 3.5 to 4.5; subject to the proviso that if the composition is a fruit-containing liquid having a fruit content of 25 to 100% by weight and an acid content of at least 5g/litre (calculated as tartaric acid), then it contains less than 2g/litre of dissolved calcium phosphate.
46. The method as claimed in claim 44 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.
47. The method as claimed in claim 44 in which the pH of the composition is not more than 4.
48. The method as claimed in Claim 44 in which the pH of the composition is from 3.7 to 3.9.
49. The method as claimed in Claim 44 in which the acidic liquid composition is a beverage.
50. The method as claimed in Claim 49 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.
51. The method as claimed in Claim 44 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.
52. The method as claimed in Claim 44 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.



53. The method as claimed in Claim 44 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.

45. A method of reducing tooth erosion in a human caused by acid in an orally administered composition which method comprises orally administering to said human a liquid composition comprising a calcium compound and an acidulant, wherein the calcium is present in the range 0.3 to 0.55 mol per mol of acid and the pH of the composition is from 3.5 to 4.5.

64. The method as claimed in claim 45 in which the calcium is present in an amount of at least 0.4 mol per mol of acid.

65. The method as claimed in claim 45 in which the pH of the composition is not more than 4.

66. The method as claimed in Claim 45 in which the pH of the composition is from 3.7 to 3.9.

67. The method as claimed in Claim 45 in which the acidic liquid composition is a beverage.

68. The method as claimed in Claim 67 in which the beverage is a still fruit drink, a carbonated soft drink, or a health drink.

69. The method as claimed in Claim 45 in which the acidic liquid composition is a drink concentrate for the preparation of a beverage.

70. The method as claimed in Claim 45 in which the acid is citric acid or malic acid or lactic acid or mixtures thereof.

71. The method as claimed in Claim 45 in which the calcium compound is calcium carbonate, calcium hydroxide, calcium citrate, calcium malate, calcium lactate, calcium chloride, calcium glycerophosphate or calcium formate.



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Attorney Docket No.: C70259

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Parker, D. 15 June 2001  
Serial No.: 09/125,471 Group Art Unit No.: 1614  
Filed: 19 August 1998 Examiner: S. Rose  
For: Liquid Oral Compositions Comprising a Calcium Compound and an  
Acidulant

Assistant Commissioner of Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT/RESPONSE

Sir:

In response to the Examiner's Action mailed 15 December 2000, having a shortened statutory period of 3 months, please enter the following Remarks and Amendments into the record. Enclosed herewith is a petition for a three (3) month extension of the shortened statutory period set by the Examiner and a transmittal letter for the filing of a Continuation Prosecution Application. Applicants also enclose a signed declaration by Dr. David Parker, an IDS and PTOL 1449 form for the Examiner's consideration.

REMARKS

Claims 15 to 18, 38, and 39, and 42 to 71 are in the application Entry of all the claims submitted in Applicants Response of 21 November 2000 into the CPA file is respectfully requested. It should be noted that method/use claims were present in the application upon filing and should not be considered issues that require further consideration.

Upon review of the Advisory Action the Examiner has stated " in the absence of a chart listing the described pH ranges and described mole ratios of calcium to acid of each prior art calcium fortified acidic beverage prior art reference, the composition claims are clearly anticipated if the references are silent on their inherent tooth erosion properties which are not unexpected in view of Andon as noted above". Applicant in their interview with the Examiner did submit a detailed listing of the Examples in each of the prior art references where it was possible to determine a pH of a molar ratio.

The Examiner further comments that "the methods are clearly inherent on ingestion of such calcium fortified acidic beverages of encompassed pH and encompassed mole ratios of calcium and acid.

Applicant respectfully traverses the Examiners statement that the claims are anticipated by a prior art composition, if you can not tell what was originally in it. It should be noted that the presently claimed invention is directed to methods of use, not to compositions of matter. Until the present invention there was no means available to the skilled artisan to readily determine how to reduce tooth erosion in an acidic liquid. The present invention only requires the addition of calcium to an acidic composition, not combinations of calcium with other acidulants as in the Andon et al. reference, for instance.

The Examiner in the Advisory action still seems to indicate that the present invention is directed to a reduction in the concentration of calcium (hence the "enabled lesser concentration of calcium to acid molar ratio") over that disclosed in the prior art. This is not what the present invention is directed towards.

The present invention uses calcium as a means for balancing acidity and pH within the composition. The higher the acid content, the more calcium would be required in order to stay within the defined molar ratio range. The total amount will, however be limited to some extent by the overall pH requirement. This concept is not described, nor taught by any of the prior art.

The total amount of calcium and specified acids, expressed either as w/w percentages of the composition or as absolute quantities, in the prior art compositions are not relevant to the determination of patentability unless they are expressed in such a way as to allow the calcium to acid molar ratio to be measured and that ratio falls within the range 0.3 to 0.80 (or .55) while conferring a pH in the range 3.5 to 4.5 as claimed herein.

The concept of identifying compositions which are effective against tooth erosion by reference to calcium:acid molar ratio and their pH is believed to be both novel and non-obvious over the cited references.

The Advisory Action requested that a Rule 312 Declaration be filed establishing "a difference from Andon 92/05711, Examples 3 and .... and the in vivo and in vitro enables examples herein in a side-by-side comparison performed with the art-recognized methodology/protocol of Lussi et al."

Applicant submits herein a declaration, which is believed to disclose that the comparison requested by the Examiner is not a possibility. Andon et al uses a calcium citrate malate salt form, which is typically added to a fruit-based soft drink. The acid content of the beverage to which the calcium salt is added is no stipulated, and hence the molar ratio of the calcium to total acids is no a concern, and can not be calculated (paragraph 10 of the Parker Declaration).

As explained by Dr. Parker in paragraph 11, the absolute amount of calcium present in a composition prepared according to the claims herein is not critical. It is the molar ratio of calcium to total acids. It is this recognition, *the molar ratio of calcium to total acid* in a composition, which is the heretofore unrecognized invention to reduce tooth erosion. The prior art does not disclose this, nor teach reduction of tooth erosion by use of a particular composition having these defined parameters.

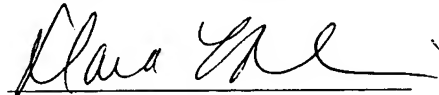
Two articles accompany these Remarks, the Hughes et al. article, and the Rugg-Gunn et al. article (cited in paragraph 12 of the Parker Declaration). The Hughes article describes a commercial product encompassed by the claims herein which showed itself to be "essentially non-erosive to human tooth enamel". In contrast, the Rugg-Gunn et al. article describing a beverage corresponding to the claims of Andon failed to show this improvement. As noted, Applicant can not calculate the molar ratio of calcium to acid in the Andon beverages in order to provide the Examiner with the requested information, it is however believed to be unnecessary as an independent article (Rugg-Gunn et al. ) teaches the skilled artisan that the Examples of Andon fail to achieve what Applicant claims.

In view of these remarks Applicant respectfully requests that the rejection to the claims under 35 USC §103 be removed.

### Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



Dara L. Dinner

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Attorney Docket No. C70259

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Myatt Parker                      21 September, 1999  
Serial No.: 09/125,471                      Group Art Unit No.: 1761  
Filed: August 19, 1998                      Examiner: S. Rose  
For: "LIQUID ORAL COMPOSITIONS COMPRISING A CALCIUM COMPOUND  
AND AN ACIDULANT"

Assistant Commissioner for Patents  
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER  
37 C.F.R. §1.97(c)

The attached list of citations on PTO Form 1449 is being submitted under the provisions of 37 CFR §1.56 and §1.97 in order to comply with the duty of disclosure. Their inclusion herein should not, however, be construed as an admission that any particular cited reference is effective prior art or that it discloses or renders obvious any aspect of the claimed invention. A copy of each cited reference is will be sent under separate cover. This statement is being filed within the time period specified in 37 CFR §1.97(d).

GB 2 207 335 (P&G) relates to calcium-supplemented beverages and beverage concentrates containing specified levels of edible organic acids and low levels of chlorine. Beverage compositions are defined in terms of percentate weight ratios of acid to calcium and chlorine. Based on the ranges given in the general disclosure and the amounts in the specific examples and transposing them into molar ratios, it is believed that there is no disclosure of a composition having a calcium to acid molar ratio in the range 0.3 to 0.55.

**GB 1 250 535 (Astra)** relates to a dry powder for preparing fruit flavour juices which confer a flavour of the same intensity as the corresponding natural fruit juice when dissolved in an aqueous medium. The powder includes a buffering system comprising at least one polycarboxylic acid and at least one alkali metal or calcium salt of a polycarboxylic acid. The acidulant component of the buffering system should be selected so as to confer a pH in the range 2.5 to 4.5. Based on the general disclosure and the specific examples, it is clear that calcium to acid molar ratios lie in the range 0.01 to 0.02 which is well outside the range 0.3 - 0.55.

**EP 0 117 653 (P&G)** relates to beverages containing specification-edible acid mixtures for improved flavour. The beverages are suitable for carbonated soft drinks having a pH from about 2.5 to about 6.5. They contain mixtures of calcium, magnesium and potassium cations and edible acids selected from citric, malic/succinic and phosphoric acids. Calculation of calcium to acid molar ratio for the several specific embodiments in the specification show that there is no disclosure of a composition having a pH in the range 3.5 to 4.5 and a calcium to acid molar ratio in the range 0.3 to 0.55.

Respectfully submitted,



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Attorney Docket No. C70259

Re: Parker, D.

Date: 4 June 2001

Serial No.: 09/125,471

Group Art Unit No.: 1761

Filed : 19 August 1998

Examiner: S. K. Rose

For: Liquid Oral Compositions Comprising a Calcium Compound and an Acidulant

**DECLARATION OF PROFESSOR DAVID MYATT PARKER**

**I, PROFESSOR DAVID MYATT PARKER DECLARE that:**

1. I have received the following academic qualifications:  
B.Sc. Honours Degree in Biochemistry in 1974 from the University of Bristol, UK.  
Ph.D. in Biochemistry in 1978 from the University of Bristol, UK.
2. I am the inventor of the subject matter contained in the above-identified patent application.
3. From 1978 to 1981, I was employed by the Department of Biochemistry at the University of Bristol Medical School as a Postdoctoral Research Fellow. In 1981, I joined Searle Research and Development Ltd., Buckinghamshire, UK where I was employed as a Research Investigator working on protein chemistry. In 1984, I joined Imperial Biotechnology Ltd., London, UK as New Product R&D Manager and Head of Quality Assurance, engaged in the manufacture of speciality enzymes for the food and pharmaceutical industries. From 1987 to 1989 I was employed as Technical Manager at Wells Soft Drinks Ltd. Worcestershire, UK, a

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company engaged in the development and manufacture of soft drink and mineral water products.

4. In 1990 I joined SmithKline Beecham Consumer Healthcare Research and Development. From 1990 to date, I have worked in the Nutritional Healthcare Category which encompasses the research and development, manufacture and marketing of healthcare drinks products. My first position within the company (from 1990 to 1992) was as Development Manager for Lucozade International in which I was responsible for all aspects of the international development programme for the leading energy drinks sold under the Lucozade brand name. In 1992, I joined the Exploration and Research Group where I held the position of Assistant Director from 1992 to 1999. From 1999 to date I have held the position of Associate Director. In my present role, I am responsible for the origination and management of a programme of research projects designed to extend the performance, acceptance and differentiation of the company's range of branded drinks products including the search for innovative science to offer unique and supportable health-related product claims.
5. I have been involved in the oral healthcare aspects associated with the consumption of acidic beverages, in particular the issue of dental erosion, since 1991. My work to provide "toothfriendly" beverage formulations conferring negligible dental erosion commenced in 1994 and remains ongoing. This work gave rise to the invention embodied in the above-identified patent application and culminated in the launch of a new commercial product "Ribena Toothkind" in the UK in April 1998. "Ribena Toothkind" is a blackcurrant berry fruit-based soft drink product. It is sold as a concentrate for dilution with water and in ready-to-drink (RTD) formulations. After an independent review of scientific data by British Dental Association (BDA) experts, this product was given BDA accreditation, confirming the validity of its claims to pose negligible risk of dental erosion. "Ribena Toothkind" was the first and is, to date, the only soft drink product to carry BDA accreditation. It has proved to be a significant commercial success in the UK. Much of my pertinent work on dental erosion, involving collaborations with academia, has been published in abstract and peer review journals.

6. In 1999, I was appointed by the Vice Chancellor of the University of Bristol as Visiting Industrial Professor to the Department of Oral and Dental Science for my substantial contributions to the development of scientific excellence in the Department. In the UK, this appointment is considered an exceptional honour.
7. I am familiar with the patent and scientific journal publications cited in connection with the above-identified patent application, many of which concern the incorporation of calcium into beverages. The majority of these publications address the incorporation of calcium as a nutritional supplement, the primary objective being to enhance the nutritional properties of beverages by maximising the amount of calcium present. The benefit of incorporating calcium to reduce the dental erosive potential of acidic beverages is also documented. US Patent No. 5,108,761 (Andon et al.), entitled "Method of Preventing Tooth Enamel Erosion Utilizing an Acidic Beverage Containing Calcium" is one such document, published shortly before I began working in the field of dental erosion. I was aware of the technology underlying the 'Andon' patent when I commenced my research activities which led to the patent application under examination.
8. The focus of both US Patent No. 5,108,761 (Andon et al) and the patent application under examination is the prevention of tooth enamel erosion. Tooth enamel erosion is a term used in the art to describe the physical result of a pathologic, chronic, localized, painless loss of dental hard tissue chemically etched away from the tooth surface by acid without bacterial involvement. Acidic conditions in which there is a pH of 5.5 or less at the tooth surface may give rise to tooth erosion. At pH values above 5.5, significant tooth erosion is not anticipated to occur.
9. The 'Andon' patent teaches a method of preventing tooth enamel erosion by supplementing erosion-producing acidic beverages with 'calcium citrate malate', a compound comprising calcium combined with specific molar ratios of malic and citric acids. Therefore, to employ the teaching of 'Andon', it is necessary to add not only calcium but also quite considerable quantities of additional acidulant in the form of malic and citric acids to a beverage that is already acidic. This is not a feature of my invention. My invention requires only the addition of calcium to an acidic composition.

10. The invention in US Patent No. 5,108,761 is expressed in claim 1 therein in terms of a stipulated calcium content falling between about 0.02 and 0.15% w/v of the beverage composition. The composition of the calcium citrate malate salt to be used in the 'Andon' beverage compositions is also an important aspect of this invention. It is expressed in terms of the molar ratio of calcium to malate to citrate and preferences are expressed in the description spanning columns 3 and 4 of the patent. These preferences translate to salts in which the molar ratio of calcium to total acids is in the range 0.8 to 1.0. According to 'Andon' the citrate malate salt is added to an acidic beverage, typically a fruit-based soft drink beverage. The acid content of the beverage to which the salt is added is not stipulated such that the molar ratio of calcium to total acids present in the beverage composition is not a feature of the invention and cannot be calculated. It is notable that 'Andon' does not teach any control of beverage pH; whilst the 'Andon' patent claims require the pH to be below 5.5, this is merely stipulated since, as indicated above, there is no appreciable dental erosion at higher pH values.
11. In contrast, the absolute amount of calcium present in compositions prepared according to my invention is not critical. What is important in my invention is the molar ratio of calcium to total acids in the final composition and this is required to fall between 0.3 and 0.8. Control of pH within the narrow range 3.5 to 4.5 is also important. It is the combination of pH control together with control over the relative amounts of calcium and acid that I found to be critical for the prevention or reduction of dental erosion in a palatable composition for oral consumption.
12. A typical example of the technology according to my invention, as claimed herein and as commercialised in the UK, provides a drink concentrate that, after dilution with water, comprises a beverage having a pH of 3.8, containing about 200 ppm of calcium and having a calcium to acid molar ratio of 0.44. This product has been demonstrated in an *in situ* human volunteer study to be essentially non-erosive to human tooth enamel. (Hughes *et al* (1999) Journal of Dentistry 27, 345-350). An embodiment of the invention as claimed in 'Andon' containing 1344 ppm of calcium and having a pH of 4.0 was tested in a similar manner but failed to demonstrate any improvement over a control drink without any added calcium citrate

malate, a key consideration being that under the test conditions neither the calcium citrate malate drink nor the control were shown to be different to water. (Rugg-Gunn *et al* (1998) Caries Research 32; 337-343). The total quantity of acid present in the test and control drinks is not stated, nor can it be calculated such that it is not possible to determine the molar ratio of calcium to total acids present.

13. Whilst the disclosure of 'Andon' did not lead me to explore the ranges disclosed in the US patent application under consideration, nor do I believe any practitioner working in the field would have been so motivated, I have nevertheless been asked to analyse the Examples in 'Andon' to ascertain whether they actually fall within my defined ranges. I shall accordingly consider each of the Examples in turn:

Example 1.

Preparation of "calcium citrate malate" (CCM) salt is described. Various quantities of CCM are added to a carbonated soft drink. No details of the constituency of the soft drink are described although the drink is presumed to be acidic since it is shown to partially dissolve a hydroxyapatite disc (a tooth enamel analogue). Progressive increases in the amount of CCM added are shown to progressively decrease erosion. The pH of the test formulations is not controlled in this experiment.

Example 2.

CCM is added to a soft drink. The composition of the soft drink which is studied in rats is not given but must be acidic. Citric acid, malic acid and calcium carbonate, all at 1 g/l, were added. The pH was neither stated nor controlled.

Example 3.

CCM is added to a range of fruit drinks prepared according to US Patent No. 4,722,847 (Heckert). No compositional details of the fruit drinks tested in this example with the addition of CCM are provided nor can they be deduced from the 'Heckert' reference. No control of pH was practiced in the Example 3 experiment nor are any pH data presented. Neither is pH a feature of the disclosure in US Pat No 4,722,847.

Example 4.

A variety of acidic fruit-based beverages, some containing CCM and some without, are assessed for enamel erosion. No compositional details of the soft drinks tested with the addition of CCM are provided such that it is not possible to calculate calcium to acid molar ratios. The pH of the test beverages is not given nor is it controlled.

14. In summary, it is not possible to derive from the information provided in the 'Andon' Examples whether any of the CCM-containing compositions had either pH values or a calcium to acid molar ratio falling within the ranges I established in defining the boundaries of my invention and which are claimed in the above-identified patent application. It is the provision of compositions in which a defined ratio of calcium to total acid is combined with pH control that underlies my invention as claimed. The preparation and use of compositions defined in terms of these claimed parameters are neither taught nor contemplated in the cited patent and scientific journal references.
15. I confirm that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true, and further that the statements are made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code and that such wilful statements may jeopardise the validity of the above-identified patent application or any patent issued thereon.

*David Myatt Parker*

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David Myatt Parker

Dated : 4th June 2001